MedSun Newsletter #67, December 2011

Articles

Using Scientific Research Data to Support Pediatric Medical Device Claims: A Public Dialogue

Print Item
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Workshops and Conferences

The Food and Drug Administration is announcing a public workshop entitled: *Using Scientific Research Data to Support Pediatric Medical Device Claims: A Public Dialogue*.

The purpose of the workshop is to receive public comment on the use of scientific research data, including published scientific literature, to extrapolate effectiveness claims from adults to children and between pediatric subpopulations in order to support and establish pediatric indications for medical devices. The workshop format will include small group breakout sessions to encourage the exchange of ideas between participants, so we're looking to have broad representation from outside the FDA.

FDA seeks representation from the pediatric medical device industry, consumers, and health care providers.

Additional Information:

Public Workshop - Using Scientific Research Data to Support Pediatric Medical Device Claims, December 5, 2011
http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm278053.htm.[7]

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Improperly Discarded *Sharps* Can Be Dangerous

Print Item
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FDA Consumer Update

Many people use needles, syringes and lancets - called "sharps" - to manage their medical conditions at home. These conditions include diabetes, allergies, infertility, arthritis, hepatitis, HIV, blood clotting disorders, migraines and cancer. Sharps are also used to give medication to pets and farm animals. Unfortunately, many sharps used outside of a doctor’s office or hospital are thrown in the household trash, and that’s hazardous. The Food and Drug Administration (FDA) has created a new web section with information about the safe disposal of needles and other sharps.

Additional Information:

FDA Consumer Update. Improperly Discarded 'Sharps' Can Be Dangerous. November 8, 2011. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm278763.htm[9]

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CareFusion EnVe Ventilators: Class I Recall - Potential for Interruption of Patient Ventilation

Print Item
E–mail Item

FDA MedWatch Safety Alert

FDA notified healthcare professionals of a Class I recall of all EnVe Ventilator model 19250-001, manufactured between December 2010 and May 2011, due to potential defects that can interrupt ventilation to the patient. The issues include: a potential delay in resuming ventilation after reconnection; a potential automatic reset; and a potential for disconnection during transport. Failure to adequately ventilate may lead to hypoxia or hypercarbia, which may result in serious neurological injury or death. CareFusion is contacting facilities to coordinate hardware and software updates for affected ventilators.

Additional Information:

FDA MedWatch Safety Alert. CareFusion EnVe Ventilators: Class I Recall - Potential for Interruption of Patient Ventilation. November 4, 2011. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm278677.htm[11]

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Mizuho OSI Modular Table Systems: Class I Recall - Reports of Patient Injury

Print Item
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FDA MedWatch Safety Alert

FDA notified health professionals of a Class I Recall of Mizuho OSI Modular Table Systems because of reports of patient injury related incidents. The incorrect removal of the T-pins that support the bottom base, instead of the T-pins that support the top, may result in patients falling to the floor. Another potential concern is unexpected movement/tilting of the table which may result in unanticipated movement and/or patient falls during surgery. Patient falls or unanticipated movement may result in serious injury or death. Mizuho issued a field advisory notice providing warnings and recommendations for safe use of the Mizuho OSI Modular Table Systems including performing a verification count of all the T-pins to confirm the stability of the table top.

Additional Information:

FDA MedWatch Safety Alert. Mizuho OSI Modular Table Systems: Class I Recall - Reports of Patient Injury. November 9, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm279266.htm[13]

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Webcast: Phototherapy and Cooling Therapy Device Safety in Neonatal Patients

Print Item
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MedSun Educational Materials

Please visit the Educational Materials page for a newly posted webcast entitled, *Phototherapy and Cooling Therapy Device Safety in Neonatal Patients* sponsored by KidNet and presented in September of 2011. The webcast discusses medical device adverse events associated with phototherapy and cooling therapy devices, provides information about their indications for use, placement considerations, as well as identifies safety tips and risk reduction strategies that promote neonatal patient safety with phototherapy and cooling therapy.

Presentation slides and transcripts are available for this webcast. A direct link to this program may be found under Additional Information below.

Additional Information:

Phototherapy and Cooling Therapy Device Safety in Neonatal Patients. September 22, 2011. MedSun Educational Materials.
http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/ucm280655.htm[15]

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Highlighted MedSun Reports

Highlighted Reports

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This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period September 1 through September 30, 2011. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

CARDIOVASCULAR

Device:
Type: Catheter, Ablation, Rf, Cardiac
Manufacturer: St. Jude Medical
Brand: Safire Blu
Model#: A402871
Lot #: 3383732
Other #: 1304-CPS-7-25-MC-BD; FG-100020943

Problem:
The 7 FR Safire Blu Ablation Catheter would not flush after being inserted into the venous sheath into the body. The catheter was removed and another catheter from another company was used. The patient's outcome was successful with the use of another catheter.
==========
Manufacturer response for Safire Blu Ablation Catheter, 7 FR, 2.3 mm MC-BD, Safire BLU (per site reporter)
==========
A replacement catheter was given to use and the representative from St. Jude will follow up with the evaluation of the defective catheter.

Device:
Type: Catheter, Electrode Recording
Manufacturer: Boston Scientific
Brand: Polaris X
Model#: M004 7003D0
Lot #: 14476871

Problem:
The EP physician was using the Boston Scientific Polaris X catheter and stated he was unable to deflect or steer the catheter. This occurred after being in the patient. Many times the physician will check the deflection of the tips of the catheters before using them but it is undetermined if that was done with this catheter. The physician requested to use another catheter. The case was incomplete. We were unable get to the PVC's to ablate them.
==========
Manufacturer response for Polaris X, standard curve decapolar catheter. 2.5/5/2.5mm x 6F (200mm), Polaris X (per site reporter)
==========
A new replacement will be sent to our facility. He will follow up with his company to evaluate the catheter.

Device:
Type: Catheter, Intravascular, Diagnostic
Manufacturer: Cordis Corporation
Brand: Williams Right Posterior Catheter
Model#: MODC18498

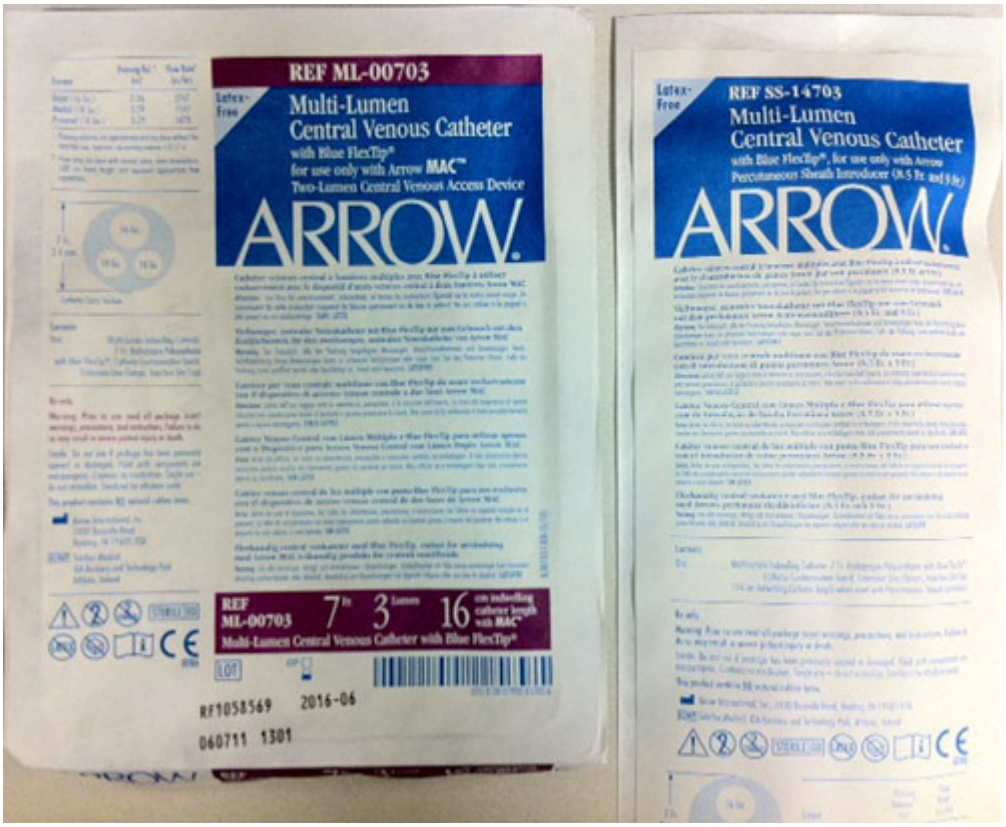
Problem:
During a cardiac cath procedure, the patient developed bilateral arm pain. Upon review of the films, a foreign body was noted in the right coronary artery (RCA). After pictures and the diagnostic catheter was reviewed by procedure physician and the intervention MD, it was determined to be the tip of a 4Fr Williams right posterior (WRP) catheter. An intervention to remove the catheter tip was performed. The foreign body was no longer observed and the patient denied any further pain.

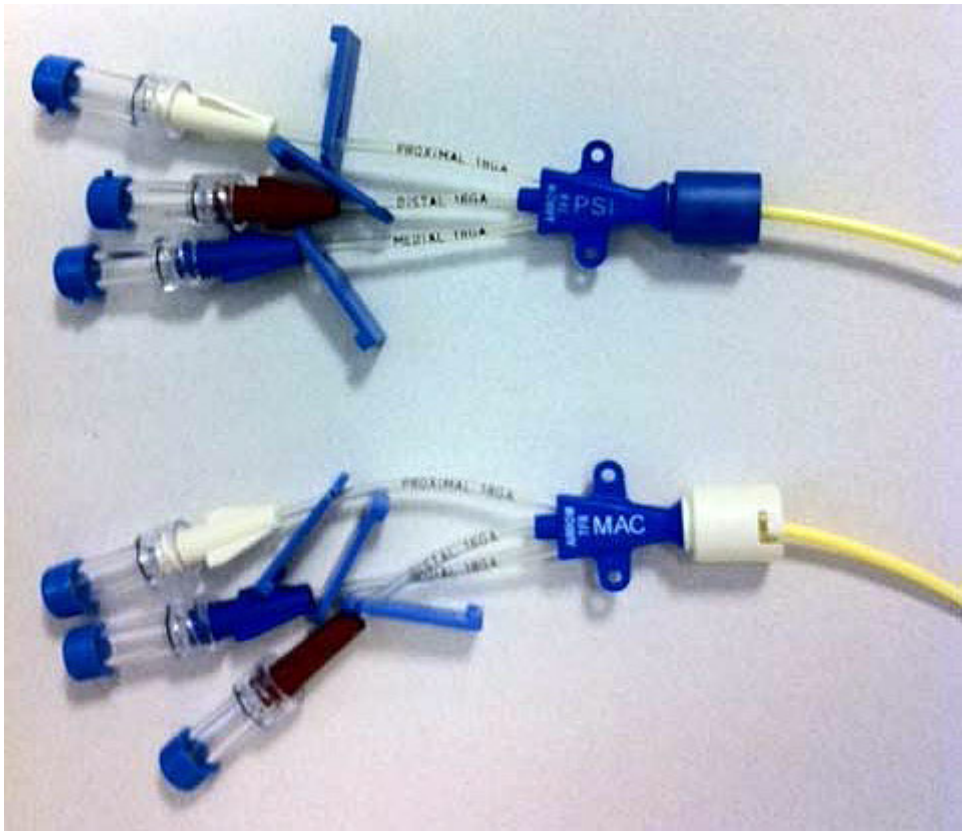
Device:
Type: Catheter, Percutaneous
Manufacturer: Arrow International, Inc.
Brand: Multi-lumen Central Venous Catheter With Blue Flextip
Model#: ML-00703
Lot #: RF1060005

Problem:
An emergent trauma patient was admitted via the Emergency department, where an Arrow PSI (percutaneous sheath introducer from kit ASK-09903-MGH2) introducer was placed for access. No catheter was inserted via the access device at the time of placement. The patient was emergently transferred to the OR for surgery. The anesthesia providers elected to place a triple lumen catheter (Multi-lumen central venous catheter, REF ML-00703) via the in-situ introducer to augment IV access for the surgical procedure. The catheter inserted via this access device was intended to be used with the Arrow MAC two-lumen central venous access device from kit ASK-11142-MGH3. The device that should have been inserted into the in-situ introducer was Multi-lumen central venous catheter (REF SS-14703). The error was not immediately apparent to the anesthesia team because both types of catheter fit both types of access device and lock interchangeably. This could potentially have been a problem with drug delivery or location of the catheter in the patient due to the size. These devices are stored in separate bins, but it would be helpful if the manufacturer changed the packaging and included bolder packaging to make the difference easier to detect. The patient was not compromised in any way. We also have photos to share and have educated staff due to the similar packaging.

See device images:


REF ML-00703
Latex-Free
Multi-Lumen
Central Venous Catheter
with Blue FlexTip®
for use only with Arrow MAC™
Two-Lumen Central Venous Access Device
ARROW.
REF
ML-00703
7 Fr.
3 Lumen
16 cm indwelling catheter length with MAC®
Multi-Lumen Central Venous Catheter with Blue FlexTip®
LOT
RF0129395
2016-01


REF ML-00703
Latex-Free
Multi-Lumen
Central Venous Catheter
with Blue FlexTip®
for use only with Arrow MAC™
Two-Lumen Central Venous Access Device
ARROW.
REF
ML-00703
7 Fr.
3 Lumen
16 cm indwelling catheter length with MAC®
Multi-Lumen Central Venous Catheter with Blue FlexTip®
LOT
RF1058569
2016-06
060711 1301
REF SS-14703
Latex-Free
Multi-Lumen
Central Venous Catheter
with Blue FlexTip®, for use only with Arrow
Percutaneous Sheath Introducer (8.5 Fr. and 9 Fr.)
ARROW.



Device:
Type: Catheter, Percutaneous
Manufacturer: Abbott Vascular
Brand: Viking
Lot #: 1051191
Cat #: 1001896-06

Problem:
It was noticed that the catheter was kinked before removal from the package. Please note that this report could not be filled out fully, as the tech did not give complete information. The package on this device was not kept and this device was not used on the patient. A new catheter was used and worked.

Device 1:
Type: Catheter, Percutaneous
Manufacturer: Arrow International
Brand: Radial Artery Catheterization Set
Model#: RA-04020
Lot #: CF1070769

Device 2:

Type: Catheter, Percutaneous
Manufacturer: Arrow International
Brand: Radial Artery Catheterization Set
Model#: RA-04020
Lot #: CF1070769

Device 3:
Type: Catheter, Percutaneous
Manufacturer: Arrow International
Brand: Radial Artery Catheterization Set
Model#: RA-04020
Lot #: CF1070769

Problem:
This report is to document that there have been multiple arterial line catheters with wire malfunctions that resulted in kinking and the inability to thread wire, advance catheter and to retract the wire. One wire we saved has a chamber kink and two saved wires have external kinks. It appears the devices are from the same lot. There was no adverse outcome to the patient as a result of these device malfunctions.

Device:
Type: Catheter, Percutaneous
Manufacturer: Arrow
Brand: Multi-lumen Central Venous Catheterization Kit With Blue Flextip® Arrowguard Blue® Catheter
Lot #: RF1069249
Cat #: AK-25703-A

Problem:
Upon establishment of central line placement, the physician was removing the guidewire from the right femoral vein. The guide wire was withdrawing and unraveled/uncoiled; it was no longer intact.

Device:
Type: Catheter, Ptca, Scoring
Manufacturer: Angiocore, Inc.
Brand: Angiosculpt Ex
Lot #: F11050032
Cat #: 2034-2010

Problem:
Device was difficult to remove from vessel after intervention, then stuck in guide catheter, and distal portion of balloon and wire broke off within the guide catheter.

Device:
Type: Console, Cryoablation
Manufacturer: Medtronic, Inc.
Brand: 104a2 Gen Iv Cryoconsole
Model#: 16000

Problem:
The Medtronic Cryo machine (N-547 Console 104A2 GEN IV CryoConsole US CAN) malfunctioned in the mapping mode. The alert was concerning. This is not the first time we have had alerts with the mapping functionality. Ablation Mode is functioning well. There have been several different alerts during several different cases. The company has taken all the catheters that we used with malfunction alerts. They are going to QA the Freezor Catheters & umbilical injection cables. We are not sure if it is a catheter or console issue. Alerts occur with different catheters and always in mapping function. The problem remains intermittent. It worked well in mapping mode the next week and then failed the following week. With this event, they were able to complete the case and there was no harm done to the patient.
==========
Manufacturer response for Medtronic Cryo machine (N-547 CONSOLE 104A2 GEN IV CRYOCONSOLE US CAN, CONSOLE 104A2 GEN IV CRYOCONSOLE US CAN (per site reporter)
==========
Inspection following 50012 errors during case. Disposables (coaxial umbilical and catheter) have been sent back to Medtronic for quality inspection. Tested console with numerous Freezor test catheters and coaxial umbilical cables. Used mapping in each test and went from mapping to ablation. No errors were reproduced in the same room the console is normally operated in. Vacuum system operated normally and test cases were completed without issue. Tested power supply voltages, temperature calibration, sub-cooler temperature, and all other values of console. No calibrations were required, all readings were within specifications. Replaced (2) auto connection boxes rev 04 with new auto connection boxes, rev 05. Replaced ECG leads with new cables. Returned console to service.

Device:
Type: Electrode, Electrocardiograph
Manufacturer: MedLine Industries, Inc.
Brand: Neonatal 1. 5Mm Radiotranslucent
Model#: MDS61115R
Lot #: 110517

Problem:
The toddler handed her mom a piece of the prewired cardiac monitoring lead. The electrode end was still on the skin. The piece that came off is a 3 cm x 5 mm hard plastic piece (DIN connector) which became disconnected from the wire. This is the end that goes into the monitor. It would take a lot of force to pull this out. It looks like the wire slid out from this plastic piece at

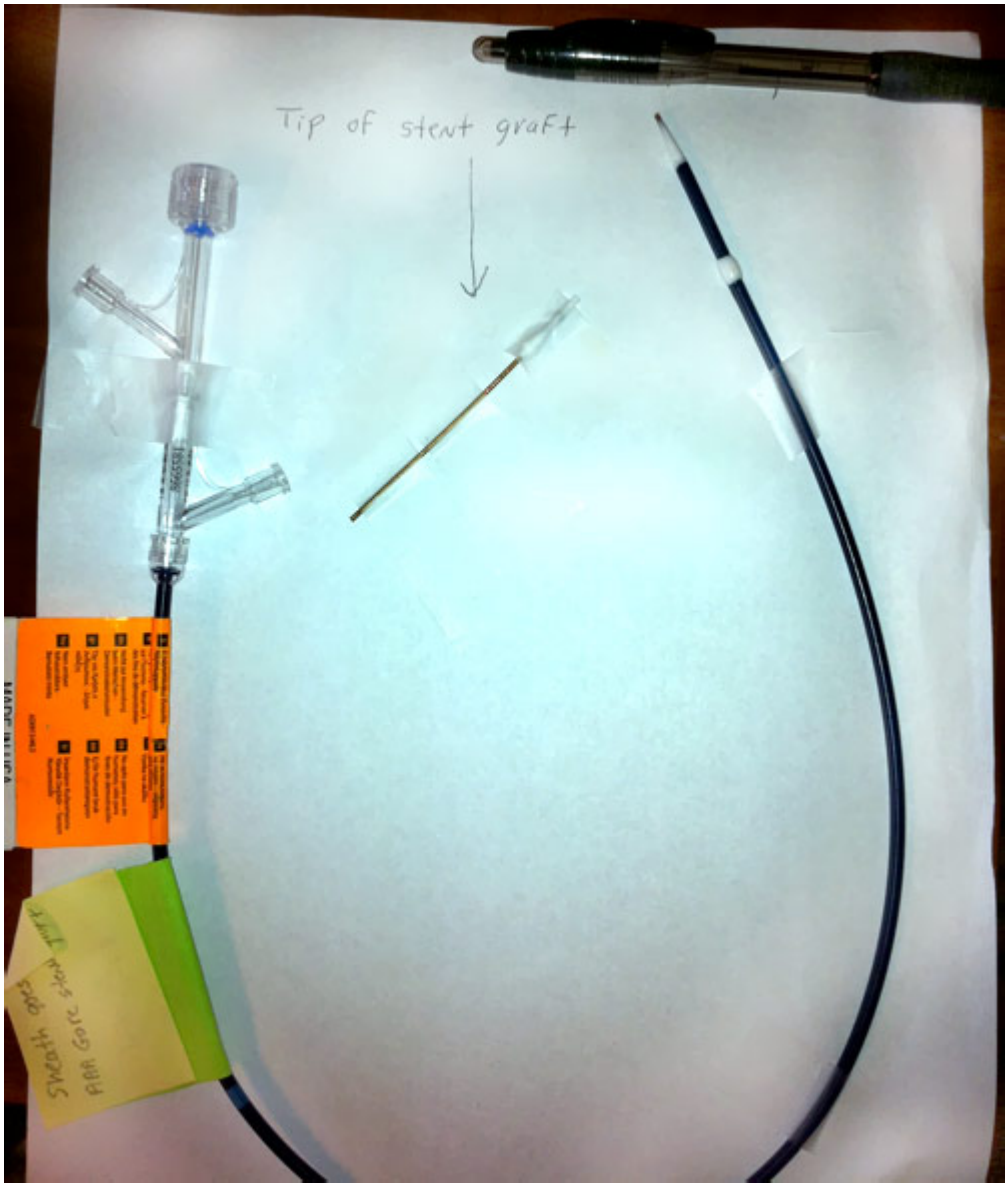
the end. The small piece can be a choking hazard. Toddler's pull at equipment, but this type of event where the lead disconnects from the lead should not be able to occur so easily. It was replicated by the nurses. Our Materials Management told me that they had problems in the past with the leads from this company.

Device:
Type: Endovascular Graft, Aortic Aneurysm
Manufacturer: W L GORE & Associates, Inc.
Brand: Excluder Contralateral Limb
Lot #: 9063472
Cat #: PXC141200

Problem:
The patient was admitted for repair of an aortic stent graft originally performed 11 years ago that had developed a type 3 endoleak. This was due to separation between the left iliac arm of the stent from the main aortic portion of the stent. This repair was performed percutaneously using a Gore Excluder Abdominal Aortic Aneurysm (AAA) Endoprosthesis in Interventional Radiology. Upon completion of the procedure, X-ray angiography indicated the graft was in good placement. However, follow up CT scans were performed to assess the status of the repair and the radiology report indicated there was a 7 cm radiopaque linear density within the abdominal aortic lumen with the tip near the proximal aspect of the graft extending cranially into the thoracic aorta. Pressure is applied on the introducer of the device at the tip where it deploys. The wire broke from the main part of the introducer and the 7cm white distal tip was seen on CT and remains in the patient. This was not able to be seen on fluoroscopy, but only afterward on the CT scan. The surgeon then notified Risk Management.

The surgeon's dictated report indicated that he changed the delivery catheter with another - he felt that the tip of the 12 French sheath was damaged from trying to push it up with force. *It is a single piece stent set. The doctor feels the patient will be stable and will not remove it since it is an endovascular device. There was no adverse outcome to the patient.
==========
Manufacturer response for Thoracic Endograft, Gore Excluder - Contralateral Limb (per site reporter)
==========
They could not identify the device in the radiographs.

See device image:



Device:
Type: Introducer, Catheter
Manufacturer: Arstasis, Inc.
Brand: Axera Access System
Cat #: AXE60

Problem:
Arstasis device footplate would not fold down resulting in removal of the device. Patient had femoral artery oozing and bleeding after access was obtained, after gaining access with placement of sheath there continued oozing around the sheath. Post procedure exam and cineangiography did not show extravastion of dye or dissection. There was no adverse outcome to the patient.

==========
Manufacturer response for Arstasis closure device, Arstasis (per site reporter)
==========
Has not responded the cardiac cath lab (CCL) let the rep take the product

Device:
Type: Lead, Left Ventricular
Manufacturer: Medtronic, Inc.
Brand: Attain Starfix
Model#: 4195-88 cm
Other #: UPN # 00885074511955

Problem:
The patient was in the process of getting a Bi-ventricular ICD implant. The Attain Starfix left ventricular (LV) lead became caught on itself in the coronary sinus and appeared on X-ray to be knotted. The physician was unable to get lead untangled in the coronary sinus or right atrium so the lead and Hockey Stick guide were pulled back into and through the left subclavian 9 French Sheath without harm or injury to the patient.

Device 1:
Type: Radial Artery Catheterization Set
Manufacturer: Teleflex Medical
Brand: Arrow International
Lot #: CF1057860
Cat #: RA-04020

Device 2:
Type: Radial Artery Catheterization Set
Manufacturer: Teleflex Medical
Brand: Arrow International
Lot #: CF1057860
Cat #: RA-04020

Device 3:
Type: Radial Artery Catheterization Set
Manufacturer: Teleflex Medical
Brand: Arrow International
Lot #: CF1057860
Cat #: RA-04020

Problem:
Four radial artery catheter sets were opened in preparation for inserting a radial catheter. Three of the catheters were found to have a defect close to the shoulder on the distal end of the device. All three sets were from the same lot. These three catheters were not used for fear that the defect

might cause injury to the vessel or that slivers of the catheter plastic might be left behind in the vessel. Photos of two of the catheters are available if they would be of benefit.
==========
Manufacturer response for Radial Artery Catheterization Set, Arrow International (per site reporter)
==========
The manufacturer hasn't had time to investigate.

GENERAL & PLASTIC SURGERY

Device:
Type: Antimicrobial Dressing, Picc
Manufacturer: Ethicon
Brand: Ethicon Biopatch

Problem:
While nurse was removing dressing from PICC line, the "blue" layer of the Biopatch pulled off and was wrapped around PICC line. The PICC line was pulled out approximately one inch while trying to remove blue layer.

Device 1:
Type: Blade, Sagital
Manufacturer: Stryker Orthopedics
Brand: System 6
Model#: 6125-127-090

Device 2:
Type: Blade, Sagital
Manufacturer: Stryker Orthopedics
Brand: System 6
Model#: 6125-127-090

Problem:
Two disposable saw blades shattered while making femoral cuts. The first broke into several pieces and all pieces were accounted for. A second saw blade was obtained and used also broke into two pieces. All pieces found and accounted for. Third saw blade used without incident. We are unable to confirm the lot numbers of these devices. There was no harm to the patient.

Device 1:
Type: Electrosurgical, Cutting &Coagulation &Accessories
Manufacturer: STRYKER ENDOSCOPY
Brand: Serfas Energy 90 S
Model#: 90 S

Lot #: 11195AE2
Cat #: 279 351 100

Device 2:
Type: Electrosurgical, Cutting &Coagulation &Accessories
Manufacturer: STRYKER ENDOSCOPY
Brand: Serfas Energy 90 S
Model#: 90 S
Lot #: 11195AE2
Cat #: 279 351 100

Problem:
Flaking noted with two Stryker Serfas Energy 90-S 3.5 mm wands during use: Wand 1) the black plastic flaked off the shaft. Wand 2) white tip chipped off. All wands with Lot number 11195AE2 were removed from the shelves, and no further ones will be ordered with this lot number.

Device:
Type: Electrosurgical, Cutting &Coagulation &Accessories
Manufacturer: Karl Storz Endoscopy
Brand: High Frequency Bipolar Cable
Lot #: 711096
Cat #: 26176 LD

Problem:
The pt was taken to the OR, draped and anesthetized. The physician had made the necessary laparoscopic incisions and was preparing to cauterize when the cautery system was not functional. The staff began to troubleshoot by exchanging cautery pens, high frequency bipolar cables and the power supply units; nothing worked. After 45min-1 hour, the physician made the decision to abort the procedure. Biomedical and engineering were called to ensure all equipment and power to the surgical suite was appropriate. During this time, the staff realized all of the high frequency bipolar cables were manufactured by the same company with the same lot number. (Biomed confirmed the power supply units were functioning appropriately and engineering confirmed the power supply to the OR suite had not been interrupted).

GENERAL HOSPITAL

Device:
Type: Aesculap Extra Long Container With Lid And Filter Paper
Manufacturer: Aesculap, Inc.
Brand: Aesculap Extra Long Hard Container System
Model#: Extra long hard container JN445, Lid JK 489 and filter paper US 751
Cat #: extra long container JN445

Problem:
During GYN surgery it was discovered that the pelvicscopy kit we thought was gas sterilized had only been cleaned and decontaminated. The hard Aesculap Instrument Container we labeled as Pelvicscopy Instrument Set had three external labels for this Aesculap Instrument Container.

Our concern and reason for filing this MedSun report is our belief that there is a design failure as to these external indicators do not properly demonstrate clear view of indicator status. The external indicators are small in size and color is dark but should be more distinct color to note steam sterilization has occurred.

As technology evolves, there are multiple varieties of indicators to allow the end user visualization if all parameters for sterilization have been met. In the past there was one indicator. The indicator color change was from white to black or a light color to a darker color. Current technology has many different color changes and sometimes the opposite of past technology. New color changes allows for subjectivity to color change. Some of the new indicators are small and difficult to visualize. Filter paper is difficult to visualize and needs to be larger in size. Staff are confused because some filter papers change colors and others do not. It is difficult for OR staff to remember all the different forms of sterilization and indicators. Color changes does not allow for staff with color blindness.

As a result, the Sterile Processing Department technician will verify/scan the external indicators of all instruments and kits prior to leaving the central supply area before transport to the OR. Also, staff awareness has been raised through education and posting of colored laminated cards in each OR room displaying the different methods of sterilization with their indicators, locks, tape, and filter paper.

NO STANDARDIZATION IN THE INDUSTRY FOR STERILIZATION COMPLIANCE

Device:
Type: Bed Mattresses
Manufacturer: Hill-Rom, Inc

Problem:
A patient was admitted to a bed. The mattress cover was noted to have "deteriorated" and subsequently allowed fluids stored in the mattress foam to seep upwards through the cover up through the sheets. Upon examination, there were breaks in the mattress liner appearing that fluid had accumulated into the foam and when the patient's weight compressed the foam, fluids seeped back through the non-intact cover staining the sheets with a fluid substance that was red-tinged.

Device:
Type: Catheter Stabilization Device
Manufacturer: Bard Medical
Brand: Statlock Picc Plus Foam
Cat #: VPPCSP

Problem:
Six StatLock devices from five patients were found to have the hard plastic "clip" portion separated from the adhesive foam portion of the device.

In two of the events, the StatLock device was included in a PICC tray received from the PICC manufacturer. In the four other events, the devices were opened separately, but the packaging was not saved. No lot numbers were documented as they are disposable devices.
In one of the events, the loss of stabilization of the PICC line resulted in the patient needing another central venous catheter placed quickly by the physician, as the patient was on inotropes and other vasoactive medications. In that instance, it was determined that the StatLock device may not have been the appropriate securement device because of the patient's small size (2.9 kg).

In all instances, it appears that the way the hard plastic clip device was joined to the foam adhesive portion failed.
==========
Manufacturer response for Catheter Stabilization Device, StatLock PICC Plus Foam (per site reporter)
==========
No response yet.

Device:
Type: Catheter, Picc
Manufacturer: Bard Access Systems, Inc.
Brand: 4Fr Dual Lumen Picc
Cat #: REVE0051
Other #: concern with other lot numbers of REU10556, REUF1089

Problem:
Between the spring of this year and late summer ten PICC lines on ten different patients had to be replaced because they have had a hole and/or were broken. These repeated holes or breaks have our IV specialist concerned of product defect.

Device:
Type: Catheter, Picc
Manufacturer: Navilyst Medical
Brand: Xcela Pasv 3f 55cm Intermediate Mst -45 Lido Kit
Model#: Product Number H965457050
Lot #: 4105215
Cat #: Order Number 45-705

Problem:
Conducting a trial of the Navilyst PowerPicc line. On three occasions, when inserting the line, the RN's noted that the catheter length markings were rubbing off of the catheter. Length

markings are integral to confirming the placement of the line.
==========
Manufacturer response for Power PICC line, XCELA PASV 3F 55CM INTERMEDIATE MST - 45 LIDO KIT (per site reporter)
==========
Requested products be sent to them. Indicated that they had not heard of this happening before. "Navilyst Medical's catheter assembly process includes verification that all printing is complete and legible, as well as testing for ink adhesion. A review of the Device History Records was performed for the reported packaging lot for any deviations related to the reported defect of the complaint. The review confirms that the lot met all material, assembly and performance specifications."

Device 1:
Type: Catheter, Picc
Manufacturer: Navilyst Medical
Brand: Xcela Pasv 3f 55cm Intermediate Mst -45 Lido Kit
Model#: H965457050
Lot #: 4105214
Cat #: 45-705

Device 2:
Type: Catheter, Picc
Manufacturer: Navilyst Medical
Brand: Xcela Pasv 3f 55cm Intermediate Mst -45 Lido Kit
Model#: H965457050
Lot #: 4128439
Cat #: 45-705

Problem:
RN was placing a PowerPICC line, and attempts to advance the wire stylet were met with resistance. The wire began to kink. The RN made an attempt to retract the wire stylet. It bunched up and was unable to be removed. The whole catheter with stylet had to be removed and another kit obtained for placement of the line. In one of these cases, the RN also reported that the black numbers and measurement marks on the catheter rubbed off during handling.
==========
Manufacturer response for Power PICC line, XCELA PASV 3F 55CM INTERMEDIATE MST - 45 LIDO KIT (per site reporter)
==========
Manufacturer has not yet had the opportunity to evaluate the product for the wire stylet issue.
==========
Manufacturer response for POWER PICC Line, XCELA PASV 3F 55CM INTERMEDIATE MST - 45 LIDO KIT (per site reporter)
==========
Manufacturer has not yet had the opportunity to evaluate the problem with the wire stylet kinking.

Device:
Type: Catheter, Picc
Manufacturer: Vygon
Brand: Premicath 1fr /28g X20 Cm
Lot #: 240311GD
Cat #: 1261.208

Problem:
Nurse was preparing a Premicath 1Fr 28 gauge central venous catheter for insertion and noted that the line was leaking. The leak was observed between the 9 and 10 cm markings on the catheter.

As this product was not actually used (due to the leak), no patient information was provided.
==========
Manufacturer response for Neonatal PICC Line, Premicath 1Fr / 28G x 20 cm (per site reporter)
==========
Awaiting results of product testing.

Device:
Type: Lights, Phototherapy
Manufacturer: Natus Medical Incorporated
Brand: Bili Light

Problem:
Nurse cut her lower thumb area on fiberglass cover of phototherapy light while moving it over infant's bed. To prevent future injuries the nurse wrote "manufacturer should cover edges of fiberglass so sharp edges are not exposed".

Device:
Type: Mediport
Manufacturer: Bard Access Systems
Lot #: 3789
Cat #: 3789

Problem:
Bard Mediport catheter was placed at different facility. One or two weeks later, when the patient went to receive their chemo through this port, the patient experienced pain and discomfort. The patient was then taken to radiology. The x-ray revealed that the catheter had broken away from the port. The patient then made an appointment to be seen here to have a catheter removed. It was discovered upon removal that the catheter had broken away from the port. It certainly

appears that this was not a clean-cut and had nothing to do with how it was implanted, but actual breakdown of the material around the port.

Device:
Type: Port, Catheter, Implanted
Manufacturer: AngioDynamics
Brand: Smartport Ct
Model#: CT80STPD
Lot #: 504373
Cat #: CT80STPD

Problem:
Patient brought to the operating room to have a fractured SmartPort removed and replaced.
==========
Manufacturer response for SmartPort CT-Injectable Port, Smart Port CT (per site reporter)
==========
Manufacturer provided RGA# for product return evaluation.

Device 1:
Type: Port, Implanted, Catheter
Manufacturer: Covidien
Brand: Autosuture Chemosite
Model#: 9 French
Lot #: N1B0746L
Cat #: 120045

Device 2:
Type: Port, Implanted, Catheter
Manufacturer: Covidien
Brand: Autosuture Chemosite
Model#: 9 French
Lot #: N1B0746L
Cat #: 120045

Device 3:
Type: Port, Implanted, Catheter
Manufacturer: Covidien
Brand: Autosuture Chemosite
Model#: 9 French
Lot #: N0MO641L
Cat #: 120045

Device 4:
Type: Port, Implanted, Catheter
Manufacturer: Covidien

Brand: Autosuture Chemosite
Model#: 9 French
Lot #: N0MO641L
Cat #: 120045

Problem:
Patient #1 had a Chemosite port implanted at the hospital for chemotherapy treatment. The patient did not show signs of bruising or complain of pain. However, a follow up x-ray showed that the catheter had broken. The catheter and port were removed at another facility.
The port and remaining piece of catheter were removed and retained by the hospital for evaluation. The catheter appears to have sheared about 2-5/8" from the port. The edge of the cut was straight and it does not appear like the catheter had burst.

It was noted that another catheter from the same lot# had recently been removed because it had cracked. Hospital records showed that 2 additional catheters from different lots had also been removed recently due to leaking or breakage.

Patient #2 had the same type of Chemosite port implanted in the spring of this year. After about a month, the catheter began leaking and the port was removed. Another port was implanted on the same patient. This port also began leaking and was removed.

Patient #3 also had the same type of port implanted. This port was removed five months later because the catheter had broken and a piece had embolized.

In addition, a fourth incident was noted from a few years ago. Patient#4 had the same type of port implanted. Subsequently, the catheter broke and the port and remaining catheter had to be removed. This port had been retained by the hospital. The catheter had broken approximately 3-1/2" from the port. The edges of the break are frayed and stretched.

There have been a total of four recent Chemosite 9 French catheters breaking after implantation, with two from the same lot. An additional incident was noted from a few years ago.

Device:
Type: Warmer, Infant Radiant
Manufacturer: Draeger Medical
Model#: RW22-1

Problem:
Caster broke while moving the device from storage spot to patient room. Examination of the wheel indicated that the stud supporting the caster was made of "pot" metal and did not appear to be of sufficient strength to be used on equipment that could be transporting critically ill neonates.
==========
Health Professional's Impression

==========
Broken wheel rendered the device unsafe for pt. use
==========
Manufacturer response for Infant resuscitation/warming device, (brand not provided) (per site reporter)
==========
All 4 casters changed as a precautionary practice

NEUROLOGY

Device:
Type: Cap, Cooling
Manufacturer: Natus Medical Incorporated
Brand: Cool-cap
Model#: COOL-CAP

Problem:
An electrical burning odor was noted at 0500. Staff swapped out open warmer, at approximately 1320 the electrical burning odor was once again noted at the bedspot. Clinical Engineering was called and about ten minutes later a popping noise (three quick pops) was heard and the screen on the cool cap machine went blank and the machine stopped functioning. The infant was immediately taken off the cool cap and moved to another bedspot. To maintain therapy the infant was transported to another facility that could offer cooling therapy.
==========
Manufacturer response for Hypothermia Units, Infant, Head, Cool-Cap (per site reporter)
==========
Manufacturer provided RGA# for device return evaluation and repair.

Device:
Type: Shunt, Central Nervous System
Manufacturer: Medtronic, Inc.
Brand: Strata Ii Programmable Vp Shunt

Problem:
Pt admitted to hospital. During hospital stay, a brain MRI was warranted and completed. Pt's programmable VP shunt settings were not checked while pt remained in inpatient status. Approximately 3 weeks later, pt developed increased headache and went to neurosurgeon's office for evaluation. At clinic, pt's VP shunt settings were checked and noted to not be at correct settings. Settings were corrected at this time. Pt did not suffer any permanent injury and did not develop any other medical conditions related to this, but there is a potential for harm for pt's who do not get their programmable VP shunt settings checked after MRI procedures done.

OBSTETRICS/GYNECOLOGY

Device:
Type: Clamp, Circumcision
Manufacturer: Covidien
Brand: Devon
Model#: 56421

Problem:
Physician did a circumcision that required pressure and use of Avitene. She felt that the clamp was defective due to oozing at circumcision site. Clamp brought down to sterile processing for evaluation. Sterile processing manager confirmed that the circumcision clamp was the correct size, but the set will be taken out of circulation because he saw that it was old and worn.

PHYSICAL MEDICINE

Device:
Type: Warmer, Infant
Manufacturer: Cardinal Health
Brand: Cardinal Heel Warmer
Lot #: (01)00630140017394
Cat #: 11460-010T

Problem:
RN was squeezing the Cardinal Infant Heel Warmer to activate the warming chemicals and it burst, spewing the contents all over her and another nurse. RN got it on her skin and said it burned for a few minutes but did not leave any lasting marks. The defect on the heel warmer package was that it split from the top. Although no other incidents have occurred to date, there is a concern about possible defective packaging.

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Special Note: The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as less than 21 years of age.

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Medical Device Problem Summaries

Summary of MedSun Reports Describing Problem with Intraocular Lenses

The intraocular lens (IOL) is an artificial lens which is implanted in the eye to restore vision after a clouded natural lens, referred to as a cataract, is removed. The IOL may be placed in either the anterior or posterior chamber of the eye. The implanted IOL corrects the visual impairment of aphakia or absence of the natural lens.

Over the past 2 years, MedSun has received 26 adverse event reports associated with the implantation of IOLs. These reports were received from 15 MedSun sites. The IOL devices identified in the reports were manufactured by Abbott Medical Optics Inc. (AMO), Alcon Research, LTD, Bausch & Lomb Inc , and Hoya Surgical Optics, Inc.
The reports were submitted during the time frame of October 2009 through July 2011.

The reported device problems were:

- 12 reports described a broken Haptic
- 6 reports listed a defective or broken lens
- 5 reports listed a defective Haptic
- 1 report described a lens cartridge deployment issue which resulted in a bent Haptic
- 2 reports listed unknown device issues

The reported patient problems listed were:

- 18 reports involved the use of a second/replacement lens which required additional surgery time
- 1 report stated a second surgery was needed
- 1 report described the need for an additional procedure

Of the reports that listed patient age, the age range was from 24 years through 91 years. Of the reports that listed patient gender, a total of 15 reports involved female patients and a total of 8 reports involved male patients.

The MedSun reports summarized above, in addition to manufacturer, healthcare, and voluntary reports contributed to FDA awareness of the device problems.

The following recalls are associated with intraocular lenses (IOL) since 2009. The MedSun-reported events may, or may not, be involved in the recalls listed.

Recall Number: Z-2802-2011
Date Posted: July 14, 2011
Product: iSert Intraocular Lens (Model PC-60AD)
Code Information: All serial numbers of I-ISO Model FC-60AD & PC-60AD lenses shipped to the U.S. and affected by this recall.

Recalling Firm/Manufacturer: Hoya Surgical Optics, Inc.
Action: Hoya Surgical Optics Inc. sent an "URGENT MEDICAL DEVICE REMOVAL" letter dated June 22, 2011 to all affected customers. The letter identifies the product, problem, and the actions to be taken. The letter instructs customers to quarantine affected product and return to HSO at their earliest convenience. Shipping instructions are included in the letter. Customers are to complete an Effectiveness Check Questionnaire and fax it to 1-909-680-3986. Questions regarding the recall process are directed to Hoya Customer Service at 1-866-750-5870 or e-mail at customercare@hoyasurgopt.com
Distribution: Nationwide Distribution
Online Link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=101699

Recall Number: Z-2801-2011
Date Posted: July, 14, 2011
Product: iSymm Intraocular Lens (Model FC-60AD)
Code Information: All serial numbers of I-ISO Model FC-60AD & PC-60AD lenses shipped to the U.S. and affected by this recall.
Recalling Firm/Manufacturer: Hoya Surgical Optics, Inc.
Action: Hoya Surgical Optics Inc. sent an "URGENT MEDICAL DEVICE REMOVAL" letter dated June 22, 2011 to all affected customers. The letter identifies the product, problem, and the actions to be taken. The letter instructs customers to quarantine affected product and return to HSO at their earliest convenience. Shipping instructions are included in the letter. Customers are to complete an Effectiveness Check Questionnaire and fax it to 1-909-680-3986. Questions regarding the recall process are directed to Hoya Customer Service at 1-866-750-5870 or e-mail at customercare@hoyasurgopt.com.
Distribution: Nationwide Distribution
Online Link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=101697

Recall Number: Z-2706-2011
Date Posted: June 29, 2011
Product: Brand Name STAAR Surgical Collamer® Ultraviolet-Absorbing Posterior Chamber Single Piece Foldable Intraocular Lens Common Names Collamer single piece IOL Collamer plate haptic IOL The Device is intended to correct aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by cataract extraction. The Device is to be implanted in the posterior chamber and in the capsular bag through a tear-free capsulorhexis (circular tear anterior capsulotomy).
Code Information: CC4204BF and CC4204A
Recalling Firm/Manufacturer: Staar Surgical Co.
Action: Staar Surgical send out an URGENT - Medical Device Correction Notice to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were asked to acknowledge receipt of the letter by signing, dating, and faxing the form to Staar Surgical. For any questions call (800) 292-7902, ext 2345.
Distribution: Worldwide Distribution - USA (nationwide) and the countries of South Africa, Slovakia, Mexico, Hong Kong, and Sri Lanka
Online Link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=100868

Recall Number: Z-0605-2010

Date Posted: January 12, 2010
Product: AMO Tecnis 1-Piece Intraocular Lens (Model ZCB00)
Code Information: All serial number of tecnis 1-Piece Intraocular Lenses that were processed through lens surface treatment at the AMO PR facility between May 19 and October 16, 2009- with serial numbers ending in 0906, 0907, 0908, and 0909, and subset with serial numbers ending in 0905 and 0910. Expiration/Use By Date (YYYY-MM). 2011-05, 2011-06, 2011-07, 2011-08, 2011-09, and 2011-10.
Recalling Firm/Manufacturer: Abbott Medical Optics Inc. (AMO)
Action: Beginning on Friday, November 6, 2009, AMO began distribution of the Recall Notification Letter via Federal Express to the 874 AMO Tecnis 1-piece IOL customer accounts in the US. Included with the Recall Notification letter is a facsimile delivery confirmation that each customer was instructed to fax back to AMO to confirm receipt of the Recall Notification Letter. --- Beginning on Monday, November 9, 2009, AMO began distribution of the Recall Notification letter to the AMO Tecnis 1-piece IOL customer/distributors accounts outside the USA. "THIS RECALL NOTIFICATION DOES NOT INVOLVE TECNIS 1-PIECE IOL THAT HAVE BEEN IMPLANTED. ONCE THE HAPTICS HAVE BEEN SUCCESSFULLY DEPLOYED, THESE LENSES FUNCTION PROPERLY." Questions should be directed to an AMO Customer Service Representative at 1-877-AMO4LIFE (1-877-266-4543).
Distribution: AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, NC, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, VT, WA, WI, WV, WY, Hawaii, and Puerto Rico. INTERNATIONAL: Austria, Azerbaijan, Belgium, Canada, Switzerland, Cyprus, Czech Republic, Germany, Estonia, Spain, Finland, France, United Kingdom, Hungary, Ireland, Israel, Italy, Lebanon, Lichtenstein, Libya, Martinique, Netherlands, Poland, Palestine, Portugal, Saudi Arabic, Sweden, Slovenia, Turkey, and South Africa.
Online Link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=86507

Recall Number: Z-0591-2010
Date Posted: January 11, 2010
Product: Bausch & Lomb SoFlex SE Foldable Intraocular Lens. UPC 4001404, Rx Only, STERILE. Manufactured by: Bausch & Lomb Incorporated,
21 Park Place Boulevard, Clearwater, FL 33759. Intraocular lens indicated for primary implantation for visual correction in adult patients where the cataractous lens has been removed by phacoemulsification. The lens is intended for placement in the capsular bag.
Code Information: Model Number: LI61SE, Lot Number 4916928
Recalling Firm/Manufacturer: Bausch & Lomb Inc.
Action: Bausch & Lomb, Inc. notified consignees via phone beginning November 19, 2009 and by follow-up letter dated November 23, 2009. Titled "Urgent - Medical Device Recall", the letter instructed users to discontinue implantation of the affected product and return any unused lenses along with the enclosed acknowledgement form to the firm. For further information, contact Bausch & Lomb at 1-585-338-6612.
Distribution: Lenses were distributed to one distributor and 35 retailers. Worldwide Distribution-Distribution to Canada, Taiwan and throughout the United States.
Online Link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=86910

The following table lists the MedSun reports that are described in the device problem summary above.

Summary of MedSun Reports Describing Problem with Intraocular Lenses		
Device Manufacturer and Brand	**Device Identifiers (Model Number, Lot Number)**	**Event Description**
Alcon Laboratoies, Inc./Acrysof IOL	Model #/MA30AC, N/A	During a Cataract removal with Intaoccular Lens Implant, Dr. noticed, prior to reaching the patient, that the lens had a crimped haptic. The lens was then set off to the side and a second implant was obtained for use.
Hoya Surgical Optics, Inc./iSert IOL	Model #/PC-60AD, N/A	During PEM with IOL implant, surgeon inserted a pre-loaded IOL into patient eye and observed haptic was missing from lens. Suregon removed defective lens and completed case without incident using another IOL (same manufacturer, model # and diopter.)
Alcon Laboratoies, Inc./Acrysof IOL	Model #/SN60WS, N/A	The intraocular lens implant was defective. One of the haptics was too short (half the length that it should have been). ========== Manufacturer response for intraocular lens implant, acrysof IQ (per site reporter): They stated that they will report it to consumer affairs.
Alcon Laboratoies, Inc./Acrysof IQ IOL	Model #/SN60WF, N/A	During surgical procedure, surgeon attempted to inject intraocular lens into Right eye using cartridge. Lens appeared to have jammed in cartridge and would not release lens. Another intraocular lens implanted without difficulty.
Alcon Laboratories, Inc./AcrySof IOL	Model #/SA60AT, N/A	While inserting optic lens it crumbled and had to be removed piece by piece.
Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	After surgeon injected newly implanted lens, it was noticed one of the haptics was broken off the lens. Lens explanted and new lens implanted without incident. Manufacturer notified and sale representative to pick up defective lens. ==========Alcon Sales Representative picked up the lens. She spent time in the OR with surgeon and nursing staff. They reviewed techniques for loading cartridge and injection of lens. A faint line near the haptic was noted on occasional lenses. Representative to take this information back to Alcon for investigation.

Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	After surgeon injected newly implanted lens, it was noticed one of the haptics was broken off the lens. Lens explanted and new lens implanted without incident. Manufacturer notified and sales representative to pick up defective lens. ==========Alcon Sales Representative picked up the lens. She spent time in the OR with surgeon and nursing staff. They reviewed techniques for loading cartridge and injection of lens. A faint line near the haptic was noted on occasional lenses. Representative to take this information back to Alcon for investigation.
Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	"After surgeon injected newly implanted lens, it was noticed one of the haptics was broken off the lens. Lens explanted and new lens implanted without incident. Alcon notified, sales reprentative to pick up defective lens. ========== Manufacturer response ========== Alcon Sales Representative picked up the lens. She also spent time in the OR with Surgeon and nursing staff. They reviewed techniques for loading catridge and injection of lens. A faint line near the Haptics was noted on occasional lenses. Manufacturer representative to take this information back to Alcon for investigation"
Alcon Laboratories, Inc./SN60WF IOL	Model #/SN60WF, N/A	During insertion of Alcon SN60WF intraocular lens, the trailing haptic of the intraocular lens broke intraocularly. This was sucessfully retrieved and the entire lens cut and rotated out of the eye safely.
Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	The haptic of the intraocular lens implant broke while being implanted by the surgeon into the right eye of the patient. Surgeon removed the broken lens and replaced it with another similar lens.
Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	After surgeon injected newly implanted lens, it was noticed one of the haptics was broken off the lens. Lens explanted and new lens implanted without incidence. Complaint questionaire completed and given to Sales Representative. ========== Health Professional's Impression ========== Lens "too" warm and soft with insertion
Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	"After surgeon injected newly implanted lens, it was noticed one of the haptics was broken off the lens. Lens explanted and new lens implanted without incidence. Complaint questionnaire completed and given to Sales Representative. ========== Health Professional's Impression

		========== Lens ""too"" warm and soft with insertion"
Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	After surgeon injected newly implanted lens, it was noticed one of the haptics was broken off the lens. Lens explanted and new lens implanted without incidence. ========== Alcon Sales represetnative notified by leaving voice mail message. Lens and injector cartridge saved for representative to pick up.
Acon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	After surgeon injected newly implanted lens, it was noticed one of the haptics was broken off the lens. Lens explanted and new lens implanted without incidence. ========== Alcon Sales Representative notified of continued problem with haptic breakage. Rep will be overnighting 2 new lens injectors to try. Rep will pick up explanted lens and cartridge.
Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN60WF, N/A	Lens found to have broken haptic after implantation. Lens explanted and another lens implanted without incidence. ========== Manufacturer response for Intraocular lens implant, AcrySof IQ IOL 29.5D ==========Alcon Sales Representative notified. After procedure,it was noted that D cartridges usually are used up to +27.00 lenses and C cartridges up to +30 for SN60WF. Rep states numerous other places use D cartridges to inject the higher power lenses without incidence and did not realize the box on D cartridges stated up to +27. Rep to pick up explanted lens and cartridge.
Abbott Medical Optics, Inc./Tecnis IOL	Model #/ZA9003, N/A	MD noted upon removal from packaging that device was damaged.
Abbott Medical Optics, Inc./Tecnis 1 IOL	Model #/ZCB00, N/A	Surgeon was flushing IOL prior to implanting lens. Surgeon observed opaque white spot in the lens and rejected it. Surgeon requested another lens - same model and diopter. Second lens was successfully implanted without incident. No adverse patient event. ========== Health Professional's Impression ========== Surgeon was flushing IOL prior to implanting IOL; under microscope the surgeon observed a defect in the lens - an opaque white spot. Hence, lens could not be implanted.
Bausch & Lomb, Inc./SofPort Aspheric IOL	Model #/PC-L161AO, Lot #/4015506	During lens insertion of an elderly patient undergoing right eye cataract extraction with lens implant and vitrectomy in Ambulatory Surgery setting, the implant broke and surgeon replaced with new lens. The surgeon inspected the eye and

		completed the procedure.
Alcon Laboratories, Inc./AcrySof IOL	Model #/SA60AT, N/A	Before implantation, IOL haptic was seen as bent.
Abbott Medical Optics, Inc./Tecnis IOL	Model #/ZA9003, N/A	Patient received right lens implant early this year. No problems with surgery or follow-up care. Approximately two months later, the patient was diagnosed with pneumonia and given antibiotics at a clinic. Within 6 hours of taking meds, face began to swell. Came to our ER 5 days later, and was diagnosed with necrotizing fasciitis. Was taken to the OR four consecutive days for debridement of parapharyngeal space, right lip, face and parotid area. Cultures grew MRSA. Septic shock - treatment with vano, zosyn, clindamycin and fluconazole. Patient died on the fourth day. ========== Health Professional's Impression ========== MD unsure if this event had anything to do with the corneal lens implant from 2 months prior.
Alcon Laboratories, Inc./AcrySof IOL	Model #/MA50BM, N/A	Patient scheduled today for repositioning of the IOL. Doctor removed the IOL due to a broken haptic. The implant was freely mobile although it was well centered. When it was moved to the side it was apparent that the inferior haptic had broken off of the implant and that was the reason for the dislocation. When the iris was retracted inferotemporally the haptic was visible.
Abbott Medical Optics, Inc./Tecnis IOL	Model #/ZA9003, N/A	Lens was opened, as tech started to fold the lens, it appeared not to fold the correct way. The lens appeared to fold upward instead of down. Tech felt that if the lens was forced to fold correctly it would have broken, so the surgeon requested another lens be opened and used. This lens did not contact the patient and the second lens was used to complete the procedure. Manufacturer provided RGA for product return evaluation.
Bausch & Lomb, Inc./SofPort AO with Violet ShieldL	Model #/L161AOV, N/A Model #/L161AOV, N/A Model #/EZ-28, Lot #/H710801	The Bausch & Lomb lens injector was not functioning properly. It bent the haptics on the lenses. Physician tried two different lenses and two different injectors. Physician feels it may have been a bad lot. Problem identified prior to any patient contact. Manufacturer response (as per reporter) for Advanced Optics Aspheric Lens, SofPort AO with Violet Shield; Manufacturer provided RGA# for product return evaluation.

	Model #/Ez-28, Lot #/H820301	Manufacturer response (as per reporter) for Lens Injector, (brand not provided; Manufacturer provided RGA# for product return evaluation.
Alcon Laboratories, Inc./AcrySof IOL	Model #/MA50BM, N/A	After surgeon placed IOL in pt's eye, the haptic broke off. Haptic retrieved and both haptic and lens removed. Surgeon reported no harm to patient. Manufacturer response (as per reporter) for Intraocular Lens, (brand not provided: Taken for review.
Alcon Laboratories, Inc./AcrySof IQ IOL	Model #/SN6AT4, N/A	Intraocular lens was implanted into the left eye. Upon insertion, lens was noted to have dots/pitting along center of lens. Incision was extended and lens cutter was used to cut the lens and remove. A new lens was inserted and the incision was closed with suture. Proper procedure and instruments were used to load the lens.
Alcon Laboratories, Inc./AcrySof IOL	Model #/SA60, N/A	The lens was placed in the pt's right eye by the MD. After placing the lens, the MD noticed that the lens was cracked. The lens was removed and replaced.